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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,868	09/30/2003	Michael Slivka	DEP-5170	7650

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,868	SLIVKA ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11 and 14-41* is/are pending in the application.

4a) Of the above claim(s) *8-11,15 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,14,16-18 and 20-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2009 has been entered.

Claims 1, 14, 20, 21, 23 and 41 have been amended; claims 1, 4-11 and 14-41 remain pending. Applicants elected the species of bioabsorable materials, specifically SIS, as the repair material; cells from spinal discs as the cell type to be seeded within the repair material; bone marrow as the type of autologous medium combined with the repair material; and GDF-5 as the bioactive factor to be combined with the repair material, **with traverse** in the reply filed 4/17/2006. Per the elections claims 8-11, 15, 19 have been withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to non-elected species, there is currently no allowable generic claim. Claims 1, 4-7, 14, 16-18 and 20-41 have been considered on the merits.

Response to Remarks

Applicant's remarks have been fully considered in combination with the amendments, and each will be addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Duplicate Claim Warning

Applicant is advised that should claims 6 and 7 be found allowable, claims 14 and 16, respectively, will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two

claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Due to the amendment, claims 14 and 16 are identical in scope to claims 6 and 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-7, 14, 16-18 and 20-41are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 41 the repair material is described as "a substantially two-dimensionally shaped disc defect repair material in the form of a strip having a length, a width and a thickness..." It is submitted that any material which has a length, a width, and a thickness is necessarily a *three-dimensional* object, not two-dimensional. The description "substantially two-dimensionally shaped [material]" is unnecessary in light of the new limitations introduced into the claim. The dependent claims inherit the deficiency and thus are rejected on the same basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The amendment to claim 1 to require an active folding step prior to insertion into the disc defect has necessitated removal of the rejections under 35 USC 102.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicants have traversed the rejection of record under 35 USC 103(a) on the grounds that no one reference discloses all the limitation of the current claims. Applicants have further asserted the rationale that manipulation of the size/shape of the repair material would be optimized in order to correspond to the defect site is flawed because the site of the defect is substantially cylindrical, thus one would not form the repair material into the shape of a flat sheet. Finally, Applicants assert that the preferred embodiment in Gan comprises sintered bioactive glass as the repair material, which is not amenable to folding.

Applicants' arguments have been fully considered, but are not found persuasive.

In response to the argument that no one reference discloses all the limitations of the current claims, it is respectfully submitted that the references are applied in combination, and are only asserted to render obvious the claimed invention when taken as a whole.

In response to the argument that in optimizing the size and shape of the repair material to correspond to the size and shape of the defect site one would not produce a substantially flat, sheet-like repair material because the defect is "substantially cylindrical" it is respectfully submitted that there is no

requirement that the defect site being treated be substantially cylindrical, the size and shape of the defect may differ in each case. Furthermore, the rationale is based on the fact that one would find it *prima facie* obvious to manipulate the size and shape of the repair material such that it corresponds in shape and size to the defect, or such that the repair material *will correlate* with the shape and size of the defect upon implantation; thus the repair material need not have the exact same dimensions as the defect but rather must only be capable of conforming to the size and shape of the defect upon implantation. As such, the repair material would be routinely manipulated to a size and shape that would be appropriate for application to the defect site. It is reiterated that when the only difference between the claimed product and that taught in the prior art is a difference is size and/or shape, yet neither the size nor shape affect the function or performance of the product, the prior art product bars patentability of the claimed product. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), (for discussion of difference in size not effective to establish patentability) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (for discussion of shape being a matter of design choice when the shape does not affect the function).

In response to Applicants' argument that the preferred embodiment of Gan comprises sintered bioactive glass, it is respectfully submitted that the entire disclosure of a reference may be relied upon, not just the preferred embodiment. For the reasons of record substitution of other known materials, such as SIS, for the material of Gan, to yield predictable results, would have been *prima facie* obvious.

Therefore the arguments are not found persuasive, and the rejections of record stand.

Claims 1, 4-7, 14, 16-18 and 20-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (US Patent 5,964,807), in view of Bilbo (US 2007/0250177), Li et al (US Patent 6,764,514), Lim et al (WO 03/51239), and Moehlenbruck et al (US Patent 6,723,335).

Gan et al disclose a method for repairing spinal disc defects, comprising removing damaged tissue from the nucleus pulposus (preparing a disc treatment site), preparing a hybrid material of intervertebral cells, such as nucleus pulposus cells, and a biodegradable substrate material (providing a cell-seeded defect repair material); and inserting the hybrid material into the intervertebral space to be repaired (See col. 5, ln 12-22).

With regards to the shape of the hybrid material (defect repair material), Gan et al state the hybrid treatment material can be shaped as necessary for insertion into the defect (See Gan et al col. 9, ln 19-31); Gan et al recite a disc shape (Fig. 1), as well as a rectangular shape or a cylindrical pad. Though Gan et al do not specify dimensions of their repair material as equivalent to those currently claimed, it is submitted that modification of the defect repair material of Gan et al into a form suitable for implantation into the intervertebral disc defect, including the form of a strip having a length, a width and a thickness, wherein the thickness is at least one order of magnitude less than the width or length, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have clearly optimized the shape of the repair material so as to correlate as closely as possible with the defect site to be repaired, or such that the repair material will correlate as closely as possible with the defect site to be repaired upon implantation. One would have had a reasonable expectation of manipulating the shape of the repair material of Gan et al based on the fact that Gan et al clearly state the shape of the hybrid material can be manipulated, thus Gan et al shows manipulating the shape of the defect repair material was within the skill of the ordinary artisan. It has been held that differences in the shape of a material, when the shape would be routinely optimized based on the recognized use/need, are considered to be obvious. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)*. For the same reasons, it is further submitted that manipulation of the hybrid repair material of Gan et al into the form of a mushroom shape, if the defect site to be repaired has a mushroom shape, would be *prima facie* obvious.

Gan et al differs from some aspects of the instant invention in that they do not disclose using SIS as the substrate for the hybrid material. However, SIS was known as a suitable graft material for use in tissue defect repair, including for repair of intervertebral discs, see, e.g. Bilbo. Bilbo disclose bioengineered grafts comprised of ICL (derived from porcine SIS) for implantation into intervertebral disc defect sites (See Bilbo, Pg. 14, paragraphs 0120-0124). Like the hybrid materials of Gan et al, the ICL grafts of Bilbo can be seeded with cells and/or bioactive factors, including growth factors.

It has been held that substitution of a known element for another to yield predictable results would have been obvious to one of ordinary skill in the art. In the instant case, both Gan et al and Bilbo report methods for repairing damaged intervertebral discs, by removing the damage disc, and inserting a defect repair material into the defect site, each of the repair materials yield the same result: occlusion of the defect site, permitting regeneration of natural tissue. Thus, substitution of the SIS (as disclosed by Bilbo) for the substrate material of the hybrid material in Gan et al, would have been obvious to one of ordinary skill in the art.

Gan et al differs from some aspects of the instant invention in that while they disclose implanting the repair material into the disc defect, they do not specifically state the repair material is twisted or manipulated as part of the insertion step. However, it is submitted that one of ordinary skill in the art will recognize that twisting, folding, or otherwise manipulating the repair material may be necessary in order to successfully insert the material into the defect site (See, *e.g.* Li et al, as they disclose rolling, curling or folding (all which read on twisting) an implant material to accommodate insertion into a cavity through a small opening, at col. 4, ln 40-55). Clearly if the opening made to the intervertebral disc space is smaller than the actual repair material, it would be necessary to fold, or twist the repair material in order to manipulate it through the opening into the defect site. In such cases the repair material may be of a form wherein the material will correlate in size and shape with the defect only after implantation (i.e. such as in

a strip form, wherein the strip is folded, twisted or rolled so as to fill a voluminous cavity). The substrate materials disclosed by Gan et al, particularly the polymer foams, as well as SIS, if substituted as the substrate material, are recognized by the artisan as being flexible, and thus one would have a reasonable expectation that the materials could be manipulated, twisted or folded as necessary.

Gan et al differs from some aspects of the instant invention in that, while they disclose including bioactive factors, including transforming growth factor-beta, in the biodegradable implant material (See col. 8, ln 62-col. 9, ln 5), they do not specify the growth factor GDF-5. It is noted that Gan et al teach growth factors, including transforming growth factor-beta enhances cell growth (See Gan et al, col. 8, ln 62-66). A person of ordinary skill, in reading Gan et al, would have recognized the desirability of improving cell growth within the hybrid material. Lim et al teaches that GDF-5 is one of a finite number of growth factors included in the transforming growth factor-beta family, known to be useful for promoting cartilage growth (chondroinductive properties) (See Lim et al, Pg. 7, ln 9-23). Thus, it would have been obvious to a person of ordinary skill in the art to try GDF-5 as the particular transforming growth factor-beta protein provided to the hybrid material of Gan et al in an attempt to provide improved cell growth within the hybrid material of Gan et al upon implantation. It has been held that "a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." See *KSR International Co. v Teleflex, Inc.* 82 USPQ2d 1385 at 1390.

Finally, Gan et al differs from some aspects of the instant invention in that they do not disclose combining the repair material with autologous bone marrow prior to insertion into the defect site. However, at the time the invention was made, it was known in the art to be beneficial to include autologous bone marrow in intervertebral disc implant materials to increase regeneration *in situ* (See, e.g.

Moehlenbruck et al, col. 5, ln 6-30); thus one of ordinary skill would have been motivated to further apply autologous bone marrow to the implant material of Gan et al, for the predictable result of increasing regeneration of the disc tissue *in situ*. One would have had a reasonable expectation of successfully providing and applying bone marrow to the implant material of Gan et al because Moehlenbruck et al disclose that use of bone marrow in intervertebral disc implants was within the purview of the artisan of ordinary skill (See Moehlenbruck et al, col. 5, ln 6-30).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651